National Agency for Food & Drug Administration & Control (NAFDAC)

Public Assessment Report (PAR)

Ladfield Amikacin 500 mg/2 mL injection
Amikacin sulfate 500 mg/2 mL

A4-102059

Ladfield Global Resources Ltd

This report reflects the scientific assessment for the approval of Ladfield Amikacin injection The product was licenced on 31 March, 2026.

PART 1: ABSTRACT

Ladfield Amikacin injection, containing Amikacin sulfate manufactured at Anhui Chengshi Pharmaceutical Co Ltd, Bengbu, Anhui, China was granted marketing authorization by NAFDAC for the treatment of serious infections due to susceptible strains of Gram-negative bacteria on 31 March 2026.

Ladfield Amikacin injection is indicated for the treatment of serious infections due to susceptible strains of Gram-negative bacteria.

For details on the uses of this product and for side effects and warnings, see the summary of product characteristics (SmPC), which can be found in the NAFDAC Greenbook.

The marketing authorization of Ladfield Amikacin injection by NAFDAC is based on the review of the Common Technical Document (CTD) dossier submitted to ascertain the quality, safety, and efficacy.

All accepted presentations of Ladfield Amikacin injection have been shown in part 2 of this report. The Summary of Product characteristics (SmPC) and the approved labelling have been presented in part 3 and part 4 respectively.

Scientific discussion on the quality, non-clinical and clinical aspects of Ladfield Amikacin injection has been presented in Part 5 of this report.

The detailed steps taken to approve Ladfield Amikacin injection by NAFDAC have been presented in part 6 of this report.

No action or steps have been taken following the marketing authorization of Ladfield Amikacin injection.

PART 2: ACCEPTED PRESENTATIONS

Product Name	Active Ingredients	Pharmaceutical Form/Description	Packaging	Pack size
Ladfield Amikacin injection	Amikacin sulfate 500 mg/2 mL	Colorless solution in 3 mL BP Type II colorless glass vial.	a clear colorless or almost colorless solution packed in a 3 mL BP Type- II clear glass vial sealed with butyl rubber plug and flip-off cap. Available as 1 x 1 vial or 1 x 10 vials	1 x 1 vial, 1 x 10 vials

PART 3: SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

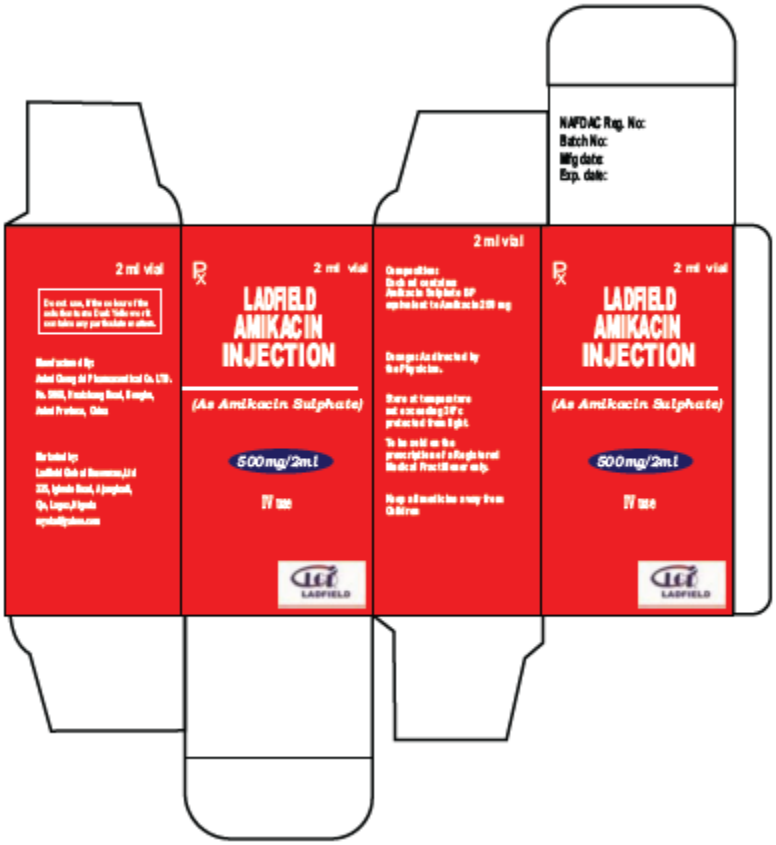
Refer to the NAFDAC Greenbook URL below for the SmPC

See: https://greenbook.nafdac.gov.ng/

PART 4: LABELLING

Primary label

Secondary label



PART 5: SCIENTIFIC DISCUSSION

5.1. About the Product

5.1.1 Name of the product

Ladfield Amikacin sulphate injection 500 mg/2 mL

5.1.2 Therapeutic indication

Ladfield Amikacin injection is indicated for the treatment of serious infections due to susceptible strains of Gram-negative bacteria.

5.1.3 Applicant

Ladfield Global Resources Limited, 335 Igbede Road, Ajangbadi, Ojo, Lagos, Nigeria.

5.1.4 Pharmaceutical form

Solution for injection

Clear, colourless to almost colorless solution.

5.1.5 Storage

Do not store above 30°C.

5.1.6 Shelf life

36 months

5.1.7 Product presentation

Ladfield Amikacin injection is presented as a clear colorless or almost colorless solution packed in a 3mL Type- II clear glass vial sealed with butyl rubber plug and flip-off cap. Available as 1 x 1 vial or 1 x 10 vial.

5.2 Drug Substance

5.2.1 Manufacturer

Amikacin sulfate is manufactured by Zhejiang Jinhua Conba Bio-pharm. Co Ltd, No. 288 Jinqu Road, Jinhua City, Zhejiang, China

The API specifications are pharmacopeial based.

Stability testing was conducted according to the requirements of NAFDAC. The proposed re-test period is justified based on the stability results when the API is stored in line with the storage statement.

5.3 Other ingredients

Other ingredients used in the formulation of Ladfield Amikacin injection include sodium citrate BP, sodium metabisulfite BP, medicinal charcoal USP, water for injection BP, all being pharmacopoeial controlled.

None of the excipients are derived from human or animal origin. TSE / BSE free certificates have been provided for the excipients.

5.4 Drug Product

5.4.1 Drug product manufacturer

Anhui Chengshi Pharmaceutical Co Ltd, No. 5068 Huaishang Road, Bengbu, Anhui,China

5.4.2 Pharmaceutical development

The objective of the pharmaceutical development was to develop a product that is analogous and therapeutically equivalent to the reference pharmaceutical product. Manufactured by Anhui Chengshi Pharmaceutical Co Ltd, the manufacturing method used was sterilization under aseptic filling techniques which were validated using three continuous batches, controlled by Standard Operating Procedures to provide stable, repeatable and reliable product quality.

5.4.3 Specification

The finished product specification is based on BP monograph. The finished product specifications include identification by chromatography, pH, related substances, extractable volume, visible particles, sub-visible particles, bacterial endotoxins, sterility, and assay. The test procedures have been adequately validated.

5.4.4 Stability

Stability studies have been conducted at 30°C/75%RH as long-term storage conditions and for six months at accelerated conditions in the packaging intended for marketing of the product. The product proved to be quite stable at these conditions, with no apparent negative trend. Based on the data submitted, the proposed shelf life of 36 months at 30±2°C/75%RH have been accepted.

5.5 Conclusion

Based on the assessment of data submitted on quality safety and efficacy, the benefit–risk profile of Ladfield Amikacin injection was acceptable for the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, and is included in the list of approved medicinal products by NAFDAC.

PART 6: STEPS TAKEN FOR REGISTRATION

The applicant, Ladfield Global Resources Limited, No. 335 Igbede Road, Ajangbadi, Ojo, Lagos, Nigeria. submitted application to the National Agency for Food and Drug Administration and Control (NAFDAC), for the registration of Ladfield Amikacin injection.

The following are the steps for the registration of Ladfield Amikacin injection

November 2023	Date of receipt of application
January 2025	Date of conclusion of assessment
November 2024	Date of inspection
01 April 2026	Date of issuance of Marketing Authorization

PART 7: STEPS TAKEN FOLLOWING REGISTRATION

No action or steps have been taken following marketing authorization of Ladfield Amikacin injection.